REMARKS

Applicants have amended their claims herein to better clarify the invention. Claim 1 recites an oral dosage form comprising a first layer and a second layer. Claim 1 is amended herein to recite a second layer comprising carboxy methyl cellulose, sodium chloride, and iron oxide. Support can be found in the Specification on Page 7 at Lines 3-7.

No new matter has been entered. Reexamination and reconsideration of the application, as amended, is respectfully requested.

Claims 1, 3-4, and 6, stand rejected under 35 USC 103(a) as being unpatentable over Kao et al. (U.S. Pub. No. 2003/0004177) in view of Mayer et al (U.S. Pat. No. 5,869,498).

Claims 2 and 5 stand rejected under 35 USC 103(a) as being unpatentable over Kao et al. in view of Mayer et al and in further view of Magruder et al. (U.S. Pat. No. 4,851,229).

Kao et al. teach a dosage form comprising an "opioid agonist and two different portions of opioid antagonist." [0012]. Kao et. al nowhere teach or suggest an oral dosage form comprising a first layer comprising oxycodone HCl in combination with dextromethorphan HBr and a second layer comprising carboxy methyl cellulose, sodium chloride, and iron oxide, as recited by Applicants' claim 1, as amended herein.

Moreover, Kao et al. actually teaches away from Applicants' claim 1, as amended herein. "A reference may be said to teach away when a person of ordinary skill, upon reading the reference . . . would be led in a direction divergent from the path that was taken by the applicant." *In re Gurley*, 27 F.3d 551, 553 (Fed.Cir. 1994). Kao et al. teach a dosage form comprising an "opioid agonist and two different portions of opioid antagonist." [0012]. This being the case, one or ordinary skill in the art following the teachings of Kao et al. would be

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motivated to form an oral dosage comprising opioid agonist and two different portions of opioid antagonist.

One of ordinary skill in the art following the teachings of Kao et al. would find not motivation to form an oral dosage that does not include an opioid antagonist. Applicants' claim 1 recites an oral dosage form that does not include an opioid antagonist. Therefore, not only does Kao et al. fail to teach or suggest the elements of Applicants' claim 1, as amended herein, Kao et al. clearly teaches away from Applicants' claim 1, as amended herein.

Mayer et al. teach a dosage form comprising a pharmacologically effective amount of a first component, a pharmacologically effective amount of a second component, and an analgesia-enhancing amount of a third component. Col. 2 / Lines 30-48. Mayer et al. teach two formulations comprising oxycodone.

In Example 10, Mayer et al. teach a dosage form comprising a oxycodone hydrochloride, acetaminophen, and dextromethorphan hydrobromide, wherein the weight ratio between the oxycodone hydrochloride and the dextromethorphan hydrobromide is 1:6.

In Example 11, Mayer et al. teach a dosage form comprising a oxycodone hydrochloride/oxycodone terephthalate, aspirin, and dextromethorphan hydrobromide, wherein the weight ratio between the oxycodone elements and the dextromethorphan hydrobromide is 1:615.

Mayer et al. teach away from Applicants' claim 1, as amended herein. One of ordinary skill in the art following the teachings of Mayer et al. would find motivation to formulation a dosage form wherein the weight ratio between the oxycodone hydrochloride and the dextromethorphan hydrobromide is 1:6 or greater. On the other hand, one of ordinary skill in

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the art would find no motivation to formulate a dosage form wherein the weight ratio between the oxycodone hydrochloride and the dextromethorphan hydrobromide is 1:5, as recited by Applicants' claim 1, as amended herein.

The Specification recites that Applicants discovered, using an acetic acid writhing test, that a "weight ratio of 1:5 of oxycodone and dextromethorphan provides optimal efficacy." Page 5 at Lines 21-22. The Specification further reads, in pertinent part, that:

> Applicants have further found that use of lesser amounts of dextromethorphan, i.e. use of weight ratios lower than 1:5, does not maximally potentiate the oxycodone. On the other hand, use of greater amounts of dextromethorphan, i.e. use of weight ratios greater than 1:5, does not provide analgesic efficacy in excess of the 1:5 weight ratio.

Page 6 at Lines 5-8.

"To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." MPEP 2143.03; *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Neither Kao et al. nor Mayer et al., singly or in combination, teach or suggest an oral dosage comprising a first layer comprising oxycodone hydrochloride and dextromethorphan hydrobromide, wherein the weight ratio between the oxycodone hydrochloride and the dextromethorphan hydrobromide is 1:5, in combination with a second layer comprising carboxy methyl cellulose, sodium chloride, and iron oxide, and wherein said oral dosage form does not include an opioid antagonist, as recited by Applicants' claim 1, as amended herein.

This being the case, Applicants respectfully submit that claim 1, as amended herein, is patentable over the combined teachings of Kao et al. and Mayer et al.

Claims 3, 4, and 6, as amended herein, depend, directly or indirectly, from claim 1, as

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amended herein. Under 35 U.S.C. § 112, fourth paragraph, "a claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers." "If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious." MPEP 2143.03; *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed.Cir. 1988). Applicants respectfully submit that claims 3, 4, and 6, as amended herein, are patentable over the combined teachings of Kao et al. and Mayer et al.

Magruder et al. teach a composition comprising a therapeutic agent and a modulating agent, wherein both the therapeutic agent and the modulating agent are disposed in a single "compartment." Col. 3 at Lines 40-50. Neither Kao et al. nor Mayer et al., nor Magruder et al. singly or in combination, teach or suggest an oral dosage comprising a first layer comprising oxycodone hydrochloride and dextromethorphan hydrobromide, wherein the weight ratio between the oxycodone hydrochloride and the dextromethorphan hydrobromide is 1:5, in combination with a second layer comprising carboxy methyl cellulose, sodium chloride, and iron oxide, as recited by claims 2 and 5, as amended herein.

This being the case, Applicants respectfully submit that claims 2 and 5, as amended herein, are patentable over the combined teachings of Kao et al., Mayer et al., and Magruder et al.

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Having dealt with all of the outstanding objections and/or rejections of the claims, Applicants submit that the application as amended is in condition for allowance, and an allowance at an early date is respectfully solicited. In the event there are any fee deficiencies or additional fees are payable, please charge them, or credit an overpayment, to our Deposit Account No. 502262.

Respectfully submitted,

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